MEETING MINUTES

DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE MEETING

August 9, 2016
St. Petersburg Marriott Clearwater
12600 Roosevelt Boulevard, North
St. Petersburg, Florida 33716

Committee Members
Jeffrey J. Mesaros, PharmD, Chair
Jeenu Philip, BPharm
Lee Fallon, PhD., BPharm
Goar Alvarez, PharmD
Board Staff
Allison Dudley, Executive Director
Alexandra Meredith, Regulatory Supervisor
Board Counsel
Lawrence Harris, Assistant Attorney General
David Flynn, Assistant Attorney General

Dr. Mesaros called the meeting to order. Committee members Jeffrey Mesaros, Jeenu Philip, Lee Fallon and Goar Alvarez were present. Also present were Michele Weizer, David Bisaillon, Mark Mikhael and Debra Glass.

Rule 64B16-27.104, Conduct Governing Pharmacists and Pharmacy Permittees; Prescription Department Managers

Mr. Harris presented the rule and stated that it is on the agenda for context with regard to the second rule on the agenda, 64B16-27.450. Mr. Harris provided the history of the Committee's work on this rule. Mr. Harris reminded the Committee that it was his intent to create a completely new rule as opposed to adding to Rule 6416-27.104.

Mr. Harris also indicated that there is new language in response to JAPC comments. JAPC asked what was meant by "documentation". Mr. Harris added

language in both rule drafts to eliminate the vagueness issue concerning "documentation". Mr. Harris asked the Board not to proceed with this rule, but to proceed instead with 64B16-27.450. Dr. Mesaros agreed and moved to the next rule on the agenda.

Rule 64B16-27.450, Prescription Department Managers

Mr. Harris walked the Board through his draft changes. He explained the changes related to fingerprinting of a new Prescription Department Manager (PDM). He explained that the language is supported by the legislative intent.

Mr. Philip suggested the language be changed to allow existing PDM's changing locations to avoid being fingerprinted again when they move to another pharmacy.

Ms. Dudley addressed the committee and stated that the fingerprints are maintained for five years, so there should not be a need to be fingerprinted every time the PDM changes locations.

Mr. Philip and Mr. Harris discussed amending the draft language to say:
"If PDM has submitted fingerprints in the previous five years, the PDM would not be required to submit those again."

Dr. Mesaros asked whether the timeframes in the rule are appropriate to allow the applicant enough time to obtain the Livescan fingerprints. Mr. Harris said he would look at the language.

The Committee discussed how to handle PDM's serving in an interim capacity.

The Committee also discussed the new responsibilities of the PDM. Dr. Weizer stated that institutional pharmacists have concerns about the 7 day initial on-site visit requirement in the draft language. Dr. Alvarez, Dr. Mesaros and Mr. Philip agreed that 7 days was too short and agreed to extend the time period to thirty days.

The Board discussed the responsibilities of the consultant pharmacists. Ms. Dudley addressed the Board and stated that the rule language does not seem to

apply the consultant pharmacists. Mr. Flynn addressed the Board and said that a PDM can only serve as PDM at one location unless the Board approves a second location. Mr. Flynn stated that there would not be PDM's working at more than 2 locations. Mr. Flynn reiterated that the language would not impact consultant pharmacists, as drafted.

Dr. Mesaros asked whether the language needed to be changed to include consultant pharmacists. Ms. Dudley asked whether the Board needed to add these responsibilities and wanted to know more about the Board's concerns in creating these additional responsibilities.

Dr. Alvarez stated that he believes the language should apply to consultants and PDM's. Dr. Mikhael stated that these new requirements would address possible issues with the PDM before something bad happens in the pharmacy.

The Board discussed the current responsibilities of the consultant pharmacist in the rule language. Dr. Mesaros asked whether the Board could move forward on the fingerprinting aspect and continue to work on the responsibilities portion of the rule.

Mr. Harris mentioned that cross-referencing this rule in consultant rule would work better than adding consultants to the current rule.

Dr. Mesaros asked whether there should be a start date for existing PDM's. Mr. Philip stated that it would be best for 6 months from the effective date of the rule.

Motion by Dr. Fallon to open rule for development and to propose the draft language but to change the 7 day requirement to 30 days, to add the language concerning existing fingerprints, and to provide a 6 month timeframe for the requirements to be effective for existing PDM's. Motion was seconded and carried.

Motion by Dr. Fallon that the proposed changes would not have an impact on small business and would not increase regulatory costs by $200,000 in one year. Motion was seconded and carried.

Rules 64B16-26.2032, 64B16-26.400

Mr. Harris addressed both rules. Mr. Harris stated that the Committee had asked that the rules be proposed but not adopted because the committee needs to discuss the rule language further. Mr. Harris walked the Committee through proposed changes in 26.400 to reduce the length of time a pharmacy intern can be registered. Mr. Harris suggested that everyone have the registration for 24 months.

Dr. Weizer explained that interns should be registered for 4 years so that they do not need to register again while they are in their program. Ms. Glass indicated that it would be better for 2 years because the schools do not notify the Board when the student is no longer enrolled. Mr. Philip recommended 5 years.

Bob Parrado addressed the committee and suggested a change to the language. Mr. Philip asked if there is authority to do a rule. Mr. Harris said there is clear authority to limit interns. Ms. Dudley asked that if there is a single timeframe for interns that the timeframe be a longer timeframe to cover the time the intern is enrolled in school.

David Flynn addressed the committee and stated that before proceeding, the Board needed to review the number of affected interns to address the impact on interns and pharmacies.

Dr. Weizer asked that the attorneys analyze whether a continuing education requirement could be added to the interns.

The rule was tabled to the next meeting.

64B16-26.2033, Approved Internship Programs

Mr. Harris explained the purpose of the rule language and explained that it is predominantly the same language that exists. It also creates standards for approving internship programs. Mr. Harris outlined the ratio for supervision of the interns. Mr. Harris stated that the suggested language that would only allow the supervision of one intern at a time, but said that could be changed depending on the Committee's intentions.

Dr. Alvarez questioned whether the supervision of one intern would apply to all programs. Mr. Harris explained that it would not apply to ACPE approved programs. Ms. Glass asked how this would affect hospital rotations and Dr. Weizer explained that this ratio applies to the foreign intern program.

Dr. Weizer stated that the ACPE requirement does not allow a preceptor to have more than 2 students at a time. Dr. Alvarez and Ms. Glass stated that there is no ratio for IPP anymore. Dr. Mesaros asked whether there would be an issue with distinguishing a class of interns. Mr. Harris said it should be the same but they have authority to create different standards. Dr. Mikhael expressed concern that if the Board puts the one to one ratio in rule for foreign interns, all programs may believe that a 1:1 ratio is the same, even for ACPE approved programs. Dr. Weizer explained the difference between these programs versus the ACPE programs. She mentioned that foreign programs often lack the clinical component that U.S. educational programs have. Therefore, the internship and the work booklet ensure that the clinical competency component is met for foreign trained applicants. Ms. Glass reiterated that serving as a preceptor and using the work manual requires significant attention to detail.

Dr. Mesaros asked whether the language could be changed to make it clear that the requirements would only apply to the program listed under subpart "c" in the draft language relating to foreign graduates. Mr. Harris discussed his intention in drafting the rule and asked about the situation in which someone may have graduated in the 90's but never took an internship. The Committee further discussed the various scenarios.

The Committee agreed to table the rule for further research and discussion.

Rule 64B16-26.351, Standards for Approval of Registered Pharmacy Technician Training Programs

Mr. Harris walked the Board through the draft language and the associated form and explained that the form has additional accrediting bodies that may be included in the rule language if the Board agrees with the list.

Dr. Alvarez asked how the list was created and Ms. Dudley explained that the accrediting bodies were taken from the U.S. Department of Education's website.

Dr. Mikhael asked about the deadline in the rule language. Mr. Harris explained his rationale in selecting the August 1st date and changing the language from "on or before" to "as of". Dr. Alvarez asked if there is an avenue for independent pharmacies to have a training program. Ms. Dudley responded that subpart three in the rule allows both independent and chain pharmacies to have employer-based programs.

Dr. Fallon made the motion to proposed with the proposing the draft language with including the list in the application in the rule language. Motion carried.

Mr. Philip made a motion that the proposed language would not have an impact on small business and would not increase regulatory cost by $200,000 in one year. Motion carried.

Rule 64B16-26.103, Continuing Education Credits; Renewal

Mr. Harris explained that the rule was brought back to the Committee for additional discussion and review of incorporated forms which were not available at the last meeting. Mr. Harris described the rationale for the "as of" language and the date in the draft language.

Dr. Mesaros expressed concern that no one should be precluded from submitting valid CE's. Dr. Weizer expressed concerns about precluding consultant pharmacists that have completed CE's in 2014. After a lengthy discussion, the Committee agreed to abandon the proposed changes to the rule.

Public Comment

No one addressed the Committee.